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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TRU-FORM OPTICS, INC., on Behalf of Itself and All Others Similarly Situated, *Plaintiff*, v. VALEANT PHARMACEUTICALS INTERNATIONAL INC., a British Columbia Corporation, *Defendant*.	Civil Action No.: CLASS ACTION CLASS ACTION COMPLAINT **JURY TRIAL DEMANDED**

Plaintiff, by and through its attorneys, based on its individual experiences, the investigation of counsel, and information and belief alleges as follows:

I. INTRODUCTION

1. Defendant Valeant Pharmaceuticals International Inc. ("Valeant") is widely known for its controversial business practices. Among these is Valeant's practice of acquiring rights to existing healthcare treatments and then implementing outsized price increases, unrelated to any increase in the costs of providing the treatment, in order to boost the company's profits. Coupled with other "aggressive" business practices—including minimizing research and development expenses (the company spends a fraction of what many other big drug companies

spend on developing new treatments)—Valeant's profits-through-price-gouging model has been described as "gamesmanship" designed to increase its stock value.

2. Valeant's practices have been called "deeply immoral," but in some cases, its practices cross the line from immoral to illegal. This case involves such a practice: an anticompetitive scheme by Valeant to monopolize the market for certain gas permeable contact lens materials and then abuse that monopoly power by raising prices far beyond prior competitive levels.

3. In August 2013, Valeant entered the market for orthokeratology ("OrthoK") lens materials—a submarket of the market for "gas permeable," or rigid, contact lens materials—by acquiring B&L Holdings ("Bausch & Lomb") for $8.7 billion. Bausch & Lomb was the second largest manufacturer of OrthoK "buttons"—the materials used to make OrthoK lenses.

4. Less than two years after it acquired Bausch & Lomb, in May 2015, Valeant successfully acquired its only competitor in the OrthoK button market—Paragon Vision Sciences ("Paragon").

5. Valeant's acquisition of Paragon gave it 100% control over the OrthoK button market, which it promptly used, in a textbook example of the abuse of monopoly power, to raise the prices on OrthoK buttons by between 61% and 143%.

6. Valeant's anticompetitive conduct has already resulted in the reduction—if not elimination—of competition in the market for OrthoK buttons, and if left unchecked, its conduct will result in no competition in the overall market for OrthoK lenses, leaving patients paying higher prices for fewer options.

II. PARTIES

7. Plaintiff Tru-Form Optics, Inc. ("TruForm Optics") is a Texas corporation that

manufactures gas permeable contact lenses, including orthokeratology lenses. Jan Svochak, the President of Plaintiff TruForm Optics, also serves as the President of the CLMA, the gas permeable lens industry's trade association, the Contact Lens Manufacturing Association ("CLMA"), in which approximately 95% of GP labs are members.

8. Defendant Valeant Pharmaceuticals is a multi-billion dollar pharmaceutical company registered under the laws of the Province of British Columbia with international headquarters in Laval, Quebec. Its U.S. Headquarters are located in Bridgewater, New Jersey. Valeant has received recent media attention for its aggressive price increases after the acquisition of two older heart drugs, and is well-known for its aggressive business practices that often skirt, and sometimes overstep, the bounds of legal conduct. According to public reports, Valeant has received subpoenas related to a criminal investigation into payments between Valeant subsidiaries and medical professionals in violation of federal law.

III. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1337 (commerce and antitrust regulation), as this action arises under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. The Court has supplemental subject matter jurisdiction of the pendant state law claims under 28 U.S.C. § 1367. The Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because the amount in controversy for the Class exceeds $5,000,000, and there are members of the Class who are citizens of a different state than the Defendant. The Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because the amount in controversy exceeds $75,000 and Plaintiff is a citizen of a different state than Defendant.

10. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c) and Sections 4 and 12 of the Clayton Act, 15 U.S.C. §§ 15 and 22, because Defendant resides, transacts business or is found within this District, and a substantial part of the events giving rise to the claims arose in this District.

IV. RELEVANT MARKET

A. ORTHOKERATOLOGY LENSES

1. Gas permeable ("GP") lenses are a type of contact lens made from a firm, durable plastic. These types of lenses are sometimes called "rigid" gas permeable lenses, although they differ from the original "hard lens" contacts in that they allow oxygen to pass through the lens and reach the cornea. GP lenses are custom made for each individual, requiring an eye care practitioner ("ECP")[1] to measure the exact shape of the cornea—often using sophisticated techniques to map eye topography—and prescribe lenses with the specific curvature, size, and corrective power to suit a particular patient's eyes.

2. Orthokeratology (or "OrthoK") refers to the use of GP lenses worn while the patient is sleeping, in order to slowly reshape the cornea and correct vision. The reshaping effects of OrthoK lenses, while not permanent, last long enough that a patient's vision remains corrected throughout the following day—without the need to wear daytime contacts or glasses.

3. OrthoK lenses are the only non-surgical treatment for myopia that permit a patient to be free from contacts or glasses during daytime hours. OrthoK lenses may also be used to slow the progression of myopia in children and teenagers, which cannot be accomplished with glasses or other types of contact lenses.

[1] ECPs can include ophthalmologists, optometrists, and opticians.

B. MANUFACTURING OF ORTHOKERATOLOGY LENSES

4. The manufacturing process for OrthoK begins with the manufacture of the FDA-approved material,[2] usually made of oxygen-permeable plastic polymers containing silicone and fluorine ("OrthoK material"). The OrthoK material is then made into small disks (called "buttons"), which are individually mounted on spinning shafts and shaped with computer-controlled precision cutting tools.

5. For approximately half the OrthoK lenses sold in the United States, the process of shaping the buttons into lenses is performed by finishing labs, such as Plaintiff TruForm Optics, which specialize in the custom manufacture of gas permeable contact lenses.

6. The finishing labs purchase OrthoK buttons from a materials manufacturer, then custom shape each lens using a particular lens design in conjunction with the patient's specific prescription information as communicated by the ECP. Many labs have their own unique lens designs—some patented—for OrthoK lenses, as well as for GP lenses in general. The labs compete with each other for customers through the creation of these designs,[3] as well as by cultivating contacts with ECPs, and by generally marketing their specialized services to ECPs and their patients.

7. Before May 2015, there were only two competitors in the market for the manufacture of FDA-approved OrthoK buttons: Paragon and Bausch & Lomb (owned by Valeant as of 2013). After purchasing Paragon in May 2015, Valeant controls 100% of the market for those buttons.

[2] *See* Section IV.C below for more detail about the FDA approval process for OrthoK lenses.

[3] Although many labs have their own unique designs, many labs also use designs licensed from other design owners.

8. In addition to monopolizing the market for OrthoK buttons, Valeant also controls the other half of the market for OrthoK lenses, which is composed of a single OrthoK product called the Paragon CRT.[4] The Paragon CRT is a "finished" lens product manufactured by Paragon, meaning that both the manufacture of the buttons and the shaping of the buttons into lenses are performed by Paragon, which then sells the lenses directly to ECPs and their patients.[5]

9. Valeant's Paragon CRT product thus competes directly with the OrthoK lenses manufactured by the finishing labs.

C. FDA APPROVAL FOR ORTHOKERATOLOGY MATERIALS

10. B&L and Paragon's—and now Valeant's—complete dominance of the market for OrthoK buttons can be explained largely by the burdensome process of gaining FDA approval for OrthoK lenses, which involves two steps. Both of these steps require enormous outlays of both time and money and create a significant barrier to entry into the OrthoK button market, which is not currently large enough to incentivize new entry given the costs.

11. Every GP lens made in the U.S. must have FDA premarket approval ("PMA") for both the materials from which it is made, and the specific design of the lens. According to the FDA:

> PMA is the most stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant

[4] CRT stands for "corneal refractive therapy." Although CRT lenses technically use different technology, the term "orthokeratology" (or OrthoK) is usually used to describe to describe all types of corneal reshaping lenses, including the Paragon CRT. *See, e.g.*, http://www.allaboutvision.com/contacts/orthok.htm. For that reason, this Complaint uses the term "OrthoK" to mean all lenses used for orthokeratology, including CRT lenses.

[5] Historically, many finishing labs have also served as distributors for Paragon CRT lenses. As of October 2015, however, Valeant notified all such distributors that it was canceling their distribution contracts.

(or owner) permission to market the device.[6]

12. Moreover, because OrthoK lenses will be worn overnight, and thus have a greater need for oxygen permeability, the materials used in OrthoK lenses—*i.e.*, the OrthoK buttons—must meet the FDA's standard for "overnight approval"—a more rigorous standard than for normal GP lenses.

13. The process to get overnight approval from the FDA takes approximately two years,[7] and can cost over $1,000,000, with just the initial application fee usually approaching $300,000.

14. In addition to approving the material for overnight use, the FDA must also approve each specific lens design intended for OrthoK use. That approval can be accomplished by obtaining a "510(k) clearance," which refers to the section of the Food, Drug and Cosmetic Act requiring device manufacturers to notify the FDA of their intent to market a new medical device that is "substantially equivalent" to one that has already been FDA approved.

15. Although obtaining a 510(k) clearance for an OrthoK lens design is substantially less burdensome than obtaining an original PMA for overnight OrthoK materials, approval of the design necessitates approval of the underlying materials. In practice, this means that finishing labs cannot get approval for their OrthoK lens designs independently, but must operate as "authorized manufacturing facilities" under the umbrella of FDA approval held by Valeant for both the material and the design of the OrthoK lens.

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[6] *See* http://www.fda.gov/Medicaldevices/Deviceregulationandguidance/Howtomarketyourdevice/Premarketsubmissions/Premarketapprovalpma/Default.Htm ("FDA Website on PMA").

[7] As the FDA itself acknowledges, although "FDA regulations provide 180 days to review the PMA and make a determination[, but] [i]n reality, the review time is normally longer." FDA Website on PMA.

16. Because the design approvals are relatively broad, however, the labs can still create and market unique lens designs—but they can do so only if they operate as "design partners" with the manufacturers that already hold the PMAs—*i.e.*, Valeant.[8] Even so, the existence of many competitors in the market for finished OrthoK lenses has allowed the labs to innovate with respect to lens designs, providing patients with a wider range of choices.

17. There are only three types of GP lens materials currently approved by the FDA for overnight wear: Paragon HDS, Paragon HDS 100, and Boston Equalens II. Two other materials—Boston XO and Boston XO_2—are also used by many U.S. finishing labs to create OrthoK lenses for international sale. After its purchase of Paragon, Valeant controls all of those materials, and the time and expense involved in getting FDA approval for OrthoK use means that Valeant thus has a complete monopoly on the market for OrthoK buttons.

V. ANTICOMPETITIVE CONDUCT

18. Less than five months after acquiring Paragon, on September 15, 2015, Valeant used its monopoly power to implement large across-the-board price hikes on OrthoK buttons, announcing the following price increases, which represented all FDA-approved OrthoK buttons for use by patients in the United States:

(a) Boston XO OrthoK and Boston Equalens II OrthoK buttons increased from $8.20 to $20.00 per button, a 143% increase.

(b) Boston XO_2 OrthoK button increased in price from $9.00 to $20.00 per button, a 122% increase.

(c) Paragon HDS and Paragon HDS-100 buttons for OrthoK increased from $12.40 to $20.00 per button, an increase of 61%.

[8] "A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act and cannot be marketed." FDA Website on PMA. Since only Bausch & Lomb and Paragon hold PMAs for OrthoK, all designs must fall under the "umbrella" of those PMAs; *i.e.*, all OrthoK designs fall under either Bausch & Lomb's approval for its "Vision Shaping Treatment (VST)" design, or Paragon's approval for its "Paragon Quadra" design.

19. At the same time, Valeant also eliminated volume discounts for both the Boston and Paragon OrthoK buttons.

20. In addition, on or around the same date, Valeant increased prices on all OrthoK buttons sold to U.S. finishing labs for use by patients outside the United States,[9] from a per-button cost ranging from $3.00–$6.25, to a per-button cost ranging from $9.00, an increase of between 44% and 200%.

21. The domestic OrthoK lens market has been growing recently, but the OrthoK market has seen much faster growth internationally, where, for example, the market for OrthoK lenses grew over 20% in a single year from 2014–2015.

22. Upon information and belief, Valeant's steep price hikes on OrthoK lenses are not only an unlawful abuse of its monopoly power in order to extract profit from customers who have no other options in the marketplace. In this case, because Valeant manufactures not only OrthoK buttons but also the Paragon CRT finished lens, the finishing labs are not only Valeant's customers, but its competitors. Thus, by increasing the costs of OrthoK buttons, Valeant will be able not only to increase its profit from button sales in the short- and medium-term, but to prevent the finishing labs from competing with it in the market for finished OrthoK lenses. In other words, Valeant's horizontal monopoly over the market for OrthoK buttons will allow it to achieve a vertical monopoly over the entire supply of OrthoK lenses in the United States and

[9] In most countries where OrthoK lenses are sold, the materials used to manufacture the lenses must either have the same FDA approvals required for sale of the lenses in the U.S., or must have similar approvals by the governments of the countries in which they are sold—approvals that take even longer to acquire than FDA approval.

many other countries.[10]

23. Indeed, confirming Valeant's intent to exclude its competitors from the OrthoK market altogether, in early December 2015, Valeant began informing finishing labs that they could no longer purchase Paragon HDS OrthoK buttons.

24. In addition, Valeant recently purchased Pelican Products, a company that manufactures, upon information and belief, 80–100% of the specialized cases used by the finishing labs to ship GP lenses (including OrthoK lenses) to ECPs—an acquisition that further tightens Valeant's grip on the vertical supply chain for OrthoK lenses.[11]

25. In the months before implementing the price increases on the OrthoK buttons, and in the months since, Valeant also made several offers to purchase finishing labs—many with substantial OrthoK business—which will allow it to increase its capacity to produce finished OrthoK lenses. Upon information and belief, once it has increased that capacity, Valeant intends to use its monopoly power to force the remaining finishing labs out of the OrthoK market altogether—leaving Valeant free to implement further price increases to patients and causing substantial harm to Plaintiff and Class members, who currently derive millions in revenue from the sale of OrthoK lenses.

[10] Moreover, as the only holder of the overnight PMAs for OrthoK buttons, Valeant has access to contact information for every ECP in the United States certified by the FDA to fit patients with OrthoK lenses, since the certification process requires that information to be submitted to Valeant. This effectively gives Valeant direct access to its competitors' customers—access which, upon information and belief, makes it even easier for Valeant to abuse its monopoly on OrthoK buttons to achieve a monopoly over the entire OrthoK supply chain.

[11] Many finishing labs worked closely with Pelican to develop their specialized cases, and Pelican's extremely high market share for the cases derives from having specifically developed their products so that, unlike, their competitors, their manufacturing process does not leave a residue on the case that can negatively affect the shipped lenses. The labs thus cannot substitute competitors' cases without incurring additional expense to remove residue before shipping lenses in them.

26. Valeant recently disclosed that it received a letter on October 16, 2015 from the Federal Trade Commission ("FTC") informing the company that the FTC is investigating Valeant's purchase of Paragon, and requesting that Valeant provide information and documentation relating to that purchase.

VI. ANTITRUST INJURY TO PLAINTIFF & CLASS MEMBERS

27. As alleged in detail above, after and due to Valeant's consolidation of the market for OrthoK buttons, there was a significant price increase for the finishing labs that are the direct purchasers of those buttons.

28. Moreover, if Valeant is successful in eliminating the labs from the OrthoK market altogether, Valeant will lessen competition in the market for OrthoK lenses by reducing both capacity and opportunities for innovation with respect to lens designs and customization. If forced out of the OrthoK market, Plaintiff and Class members will lose millions of dollars of OrthoK revenue, and patients will experience higher prices and less innovation.

29. As a direct result of Defendant's anticompetitive actions, competition in the market for OrthoK buttons has been, and will continue to be, restrained, and competition in the market for OrthoK lenses faces the threat of restrained—if not eliminated—competition.

VII. CLASS ACTION ALLEGATIONS

30. Plaintiff sues on its own behalf and on behalf of a class of persons and entities pursuant to Federal Rule of Civil Procedure 23. The Class consists of all direct purchasers in the United States of GP buttons that are FDA-approved for OrthoK uses and manufactured by Valeant or any wholly owned subsidiary of Valeant. These currently consist of the following buttons in Boston and Paragon materials:

(a) Quadra--Paragon HDS Violet

(b) Quadra--Paragon HDS 100 Yellow

(c) Boston Equalens II for OrthoK use

(d) Boston XO_2 for OrthoK use

(e) Boston XO for OrthoK use

31. The persons in the Class are so numerous that individual joinder of all members is impracticable under the circumstances of this case. Although the precise number of such persons is unknown, the exact size of the Class is easily ascertainable, as each class member can by identified by the Defendant's sales records.

32. There are common questions of law and fact specific to the Class that predominate over any questions affecting individual members, including:

(a) Whether Defendant has a monopoly on the market for OrthoK buttons;

(b) Whether Defendant gained this monopoly unlawfully;

(c) Whether Defendant's actions in acquiring Paragon violated both federal and state law;

(d) Whether consumers and class members have been damaged by Defendant's conduct;

(e) Whether Defendant should disgorge unlawful profits; and

(f) The nature and scope of injunctive relief necessary to restore a competitive market.

33. Plaintiff's claims are typical of the Class' claims, as they arise out of the same course of conduct and the same legal theories as the rest of the Class, and Plaintiff challenges the practices and course of conduct engaged in by Defendant with respect to the Class as a whole.

34. Plaintiff will fairly and adequately protect the interests of the class. Plaintiff has retained counsel who are able and experienced class action litigators.

35. Resolution of this action on a class-wide basis is superior to other available methods and is a fair and efficient adjudication of the controversy because in the context of this

litigation, no individual class member can justify the commitment of the large financial resources to vigorously prosecute a lawsuit against Defendant. Separate actions by individual class members would also create a risk of inconsistent or varying judgments, which could establish incompatible standards of conduct for Defendant and substantially impede or impair the ability of class members to pursue their claims. A class action also makes sense because Defendant has acted and refused to take steps that are, upon information and belief, generally applicable all companies in the marketplace, thereby making injunctive relief appropriate with respect to the Class as a whole.

VIII. COMMON COURSE OF CONDUCT EMANATING FROM NEW JERSEY

36. Upon information and belief, the unlawful course of conduct outlined above was created, adopted, ratified and/or implemented in the corporate headquarters of Valeant, located in Bridgewater, New Jersey. Upon information and belief, the Valeant executives responsible for the series of anticompetitive agreements outlined above are based in New Jersey and a substantial part, if not all, the anticompetitive conduct took place in New Jersey. Therefore, application of New Jersey law to a nationwide class is appropriate.

IX. CLAIMS

FIRST CAUSE OF ACTION
VIOLATION OF THE SHERMAN ACT
(15 U.S.C. § 2)

37. Each of the foregoing allegations is incorporated in this claim for relief.

38. The relevant product market is the market for OrthoK buttons.

39. The relevant geographic market is the entire United States.

40. Valeant possesses monopoly power in the market for OrthoK buttons.

41. Because the manufacture and sale of OrthoK buttons requires time-intensive and costly FDA approval, substantial barriers to entry and expansion exist in the relevant market.

42. Valeant has engaged in anticompetitive conduct to unlawfully obtain, maintain and enhance its monopoly in the OrthoK button market and to raise prices above previously competitive levels. Valeant's actions will limit competition in the market for OrthoK buttons and discourage future innovation in the overall market for OrthoK lenses.

43. There is no legitimate business justification for Valeant's conduct.

44. Plaintiff and the Class members have been injured and will continue to be injured in their businesses and property by higher prices in the OrthoK button market than they would have paid in the absence of Valeant's unlawful acts. In addition, due to Defendant's actions, Plaintiff and Class members face the threat of future injury in that Valeant's monopoly over the market for OrthoK buttons will allow Valeant to exclude Plaintiff and Class members from the OrthoK market altogether.

45. Any pro-competitive effects of Valeant's conduct are outweighed by the clear anticompetitive effects.

46. Plaintiff and the Class members are entitled to damages for their injuries, as well as an injunction that terminates the ongoing violations alleged in this Complaint and requires Valeant to divest itself of all OrthoK-related holdings acquired in its purchase of Paragon.

SECOND CAUSE OF ACTION
VIOLATION OF THE NEW JERSEY ANTITRUST ACT
(N.J.S.A. 56:9-4)

47. Each of the foregoing allegations is incorporated in this claim for relief.

48. The relevant product market is the market for OrthoK buttons.

49. Valeant transacts business throughout the United States, including New Jersey.

50. Valeant's unlawful acts were carried out at least in part at its U.S. Headquarters in Bridgewater, New Jersey.

51. Valeant has willfully obtained a 100% monopoly of the market for OrthoK buttons through its acquisition of B&L and Paragon. This purchase has eliminated competition in the market for OrthoK buttons.

52. As a result of Valeant's conduct, Plaintiff and Class members have been forced to purchase OrthoK buttons at a price substantially higher than they would have paid in the absence of this unlawful conduct.

53. Valeant's price increases following its purchase of Paragon demonstrate the success of its attempt to monopolize the market for OrthoK buttons, and its purchase of finishing labs, coupled with price increases sufficient to drive the remaining labs from the OrthoK market altogether, will have the effect of eliminating competition, discouraging innovation, and giving it a monopoly over the patient (end-user) market for finished OrthoK lenses. As a result, patients will have access to a substantially smaller selection of lens products at prices that are higher than they otherwise would be.

X. JURY TRIAL DEMANDED

54. Plaintiff hereby demands a trial by jury on all issues triable of right by jury.

PRAYER FOR RELIEF

55. WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

(a) Certification of the action as a Class Action pursuant to the Federal Rules of Civil Procedure, and appointment of Plaintiff as Class Representative and Plaintiff's counsel of record as Class Counsel;

(b) Actual damages, statutory damages, punitive and/or treble damages, and such other relief as provided by the statutes cited herein;

(c) Prejudgment and post-judgment interest on such monetary relief;

(d) Equitable relief in the form of restitution and/or disgorgement of all unlawful or illegal profits received by Defendant as a result of the anticompetitive conduct alleged in herein;

(e) An injunction restoring competitive market conditions by requiring Valeant to divest itself of the OrthoK assets of Paragon and/or B&L;

(f) Other appropriate injunctive relief;

(g) The costs of bringing this suit, including reasonable attorneys' fees; and

(h) All other relief to which Plaintiff and members of the Class may be entitled at law or in equity.

Dated: December 22, 2015

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not related to any other action, pending arbitration or administrative proceeding currently pending in any court.

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: December 22, 2015

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